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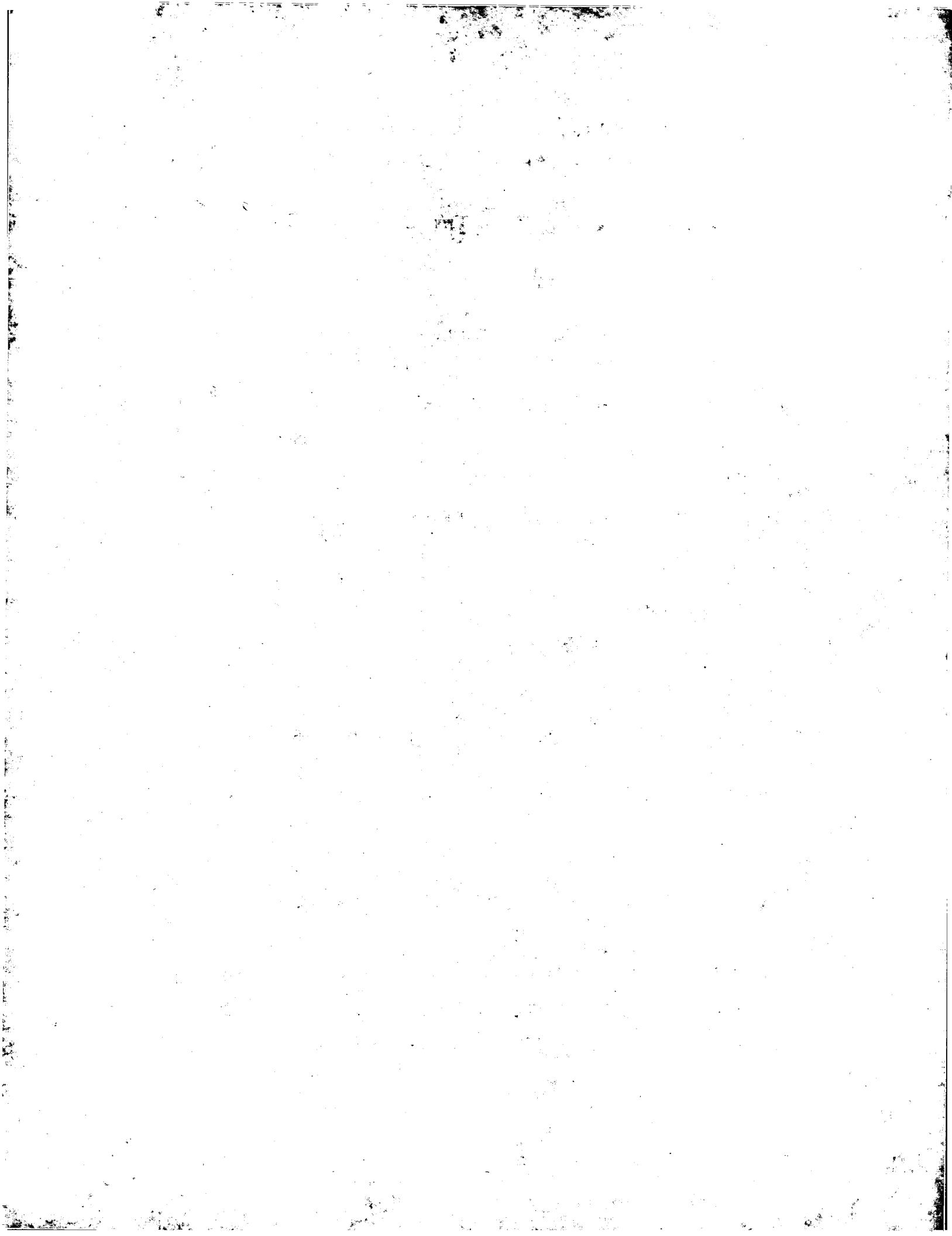
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A61P 43/00

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VN, YU, ZA, ZW.

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patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
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IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
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- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

(71) Applicant (for all designated States except US): ELI LILLY AND COMPANY [US/US]; Lilly Corporate Center, Indianapolis, IN 46285 (US).

Published:

(72) Inventors; and

— with international search report

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(74) Agents: LENTZ, Nelsen, L. et al.; Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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A3
02/019998

(54) Title: A METHOD OF TREATING WEIGHT GAIN ASSOCIATED WITH ATYPICAL ANTIPSYCHOTIC USE

WO

(57) Abstract: A method of treating weight gain associated with atypical antipsychotic use which comprises administering to a mammal in need thereof a therapeutically effective amount of N,N-dimethyl-1-[1-(4-chlorophenyl) cyclobutyl]-3-methylbutylamine hydrochloride.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/22621

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/135 A61P43/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols).
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, MEDLINE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>BLACKBURN G.L. ET AL: "Weight gain and antipsychotic medication." JOURNAL OF CLINICAL PSYCHIATRY, (2000) 61/SUPPL. 8 (36-42). , XP008005169</p> <p>page 37, right-hand column, paragraph 3 -page 38, left-hand column, paragraph 1 page 38, right-hand column, paragraphs 2,3 page 39, right-hand column, paragraph 4</p> <p style="text-align: center;">-/-</p>	1-21

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 July 2002	29/07/2002
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Bazzanini, R

INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/US 01/22621

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GREENBERG ISAAC ET AL: "Nonpharmacologic and pharmacologic management of weight gain." JOURNAL OF CLINICAL PSYCHIATRY, vol. 60, no. SUPPL. 21, 1999, pages 31-36, XP008005348 ISSN: 0160-6689 page 31, left-hand column, paragraph 1 page 33, left-hand column, paragraph 2 page 34, right-hand column, paragraphs 2-4 page 35, left-hand column, paragraph 3 ---	1-8, 11-19
P,X	WO 00 56313 A (KNOLL PHARMACEUTICAL COMPANY) 28 September 2000 (2000-09-28) cited in the application page 1, line 4-15, 24, 25 page 3, line 15-19 page 4, line 14, 15 page 7, line 12-21 page 8, line 4-14 table 1 claims 1-20 ---	1-21
P,X	KURZTHALER I. ET AL: "The clinical implications of weight gain in schizophrenia." JOURNAL OF CLINICAL PSYCHIATRY, (2001) 62/SUPPL. 7 (32-37). , XP008005160 page 32, left-hand column, paragraph 1 -right-hand column, paragraph 1 page 33, right-hand column, paragraph 2 page 36, right-hand column, paragraph 2 ---	1-21
P,X	CASEY D.E. ET AL: "The pharmacology of weight gain with antipsychotics." JOURNAL OF CLINICAL PSYCHIATRY, (2001) 62/SUPPL. 7 (4-10). , XP008005168 page 6, left-hand column, paragraph 4 page 6, right-hand column, paragraphs 3-5 page 7, left-hand column, paragraph 2 page 7, right-hand column, paragraph 2 -page 8, left-hand column, paragraph 1 tables 1,2 page 8, right-hand column, paragraph 2 -page 9, left-hand column, paragraph 3 ---	1-21
	-/-	

INTERNATIONAL SEARCH REPORT

Inte	nal Application No
PCT/US 01/22621	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	ALLISON D.B. ET AL: "Antipsychotic -induced weight gain: A review of the literature." JOURNAL OF CLINICAL PSYCHIATRY, (2001) 62/SUPPL. 7 (22-31). , XP008005159 page 24, right-hand column, paragraph 2 page 28, column 3, paragraph 2	1-21
A	US 5 436 272 A (SCHEINBAUM MONTE L) 25 July 1995 (1995-07-25) column 1, line 28-40 column 2, line 45-61 claims 1-8	1-21
A	US 5 736 541 A (HENDRIKSEN BARRY ARNOLD ET AL) 7 April 1998 (1998-04-07) column 1, line 17-34	1-21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/22621

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 1-11 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-8,11-19 relate to a method of treating weight gain associated to the use of compounds, which are defined by reference to a desirable characteristic or property, namely atypical antipsychotics. The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such products (i.e. olanzapine, risperidone, sertindole, quetiapine, ziprasidone, clozapine). In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compounds responsible of the weight gain by reference to their pharmacological profile. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the products mentioned in claim 9,21 and in the description at page 3, lines 21-24, namely olanzapine, risperidone, sertindole, quetiapine, ziprasidone, clozapine.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/22621

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte
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PCT/US 01/22621

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